§ 864.6600 Osmotic fragility test.

(a) *Identification.* An osmotic fragility test is a device used to determine the resistance of red blood cells to hemolysis (destruction) in varying concentrations of hypotonic saline solutions.

(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

[45 FR 60607, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989; 66 FR 38790, July 25, 2001]

§ 864.6650 Platelet adhesion test.

(a) *Identification.* A platelet adhesion test is a device used to determine in vitro platelet function.

(b) *Classification.* Class II (performance standards).

[45 FR 60608, Sept. 12, 1980]

§ 864.6675 Platelet aggregometer.

(a) *Identification.* A platelet aggregometer is a device, used to determine changes in platelet shape and platelet aggregation following the addition of an aggregating reagent to a platelet rich plasma.

(b) *Classification.* Class II (performance standards).

[45 FR 60608, Sept. 12, 1980]

§ 864.6700 Erythrocyte sedimentation rate test.

(a) *Identification.* An erythrocyte sedimentation rate test is a device that measures the length of time required for the red cells in a blood sample to fall a specified distance or a device that measures the degree of sedimentation taking place in a given length of time. An increased rate indicates tissue damage or inflammation.

(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

[45 FR 60608, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989; 66 FR 38790, July 25, 2001]

Subpart H—Hematology Kits and Packages

§ 864.7040 Adenosine triphosphate release assay.

(a) *Identification.* An adenosine triphosphate release assay is a device that measures the release of adenosine triphosphate (ATP) from platelets following aggregation. This measurement is made on platelet-rich plasma using a photometer and a luminescent firefly extract. Simultaneous measurements of platelet aggregation and ATP release are used to evaluate platelet function disorders.

(b) *Classification.* Class I (general controls).

[45 FR 60609, Sept. 12, 1980]

§ 864.7060 Antithrombin III assay.

(a) *Identification.* An antithrombin III assay is a device that is used to determine the plasma level of antithrombin III (a substance which acts with the anticoagulant heparin to prevent coagulation). This determination is used to monitor the administration of heparin in the treatment of thrombosis. The determination may also be used in the diagnosis of thrombophilia (a congenital deficiency of antithrombin III).

(b) *Classification.* Class II (performance standards).

[45 FR 60609, Sept. 12, 1980]

§ 864.7100 Red blood cell enzyme assay.

(a) *Identification.* Red blood cell enzyme assay is a device used to measure the activity in red blood cells of clinically important enzymatic reactions and their products, such as pyruvate kinase or 2,3-diphosphoglycerate. A red blood cell enzyme assay is used to determine the enzyme defects responsible for a patient's hereditary hemolytic anemia.

(b) *Classification.* Class II (performance standards).

[45 FR 60610, Sept. 12, 1980]

§ 864.7140 Activated whole blood clotting time tests.

(a) *Identification.* An activated whole blood clotting time tests is a device, used to monitor heparin therapy for

the treatment of venous thrombosis or pulmonary embolism by measuring the coagulation time of whole blood.

(b) *Classification.* Class II (performance standards).

[45 FR 60611, Sept. 12, 1980]

§ 864.7250 Erythropoietin assay.

(a) *Identification.* A erythropoietin assay is a device that measures the concentration of erythropoietin (an enzyme that regulates the production of red blood cells) in serum or urine. This assay provides diagnostic information for the evaluation of erythrocytosis (increased total red cell mass) and anemia.

(b) *Classification.* Class II. The special control for this device is FDA's ''Document for Special Controls for Erythropoietin Assay Premarket Notification (510(k)s).''

[45 FR 60612, Sept. 12, 1980, as amended at 52 FR 17733, May 11, 1987; 65 FR 17144, Mar. 31, 2000]

§ 864.7275 Euglobulin lysis time tests.

(a) *Identification.* A euglobulin lysis time test is a device that measures the length of time required for the lysis (dissolution) of a clot formed from fibrinogen in the euglobulin fraction (that fraction of the plasma responsible for the formation of plasmin, a clot lysing enzyme). This test evaluates natural fibrinolysis (destruction of a blood clot after bleeding has been arrested). The test also will detect accelerated fibrinolysis.

(b) *Classification.* Class II (performance standards).

[45 FR 60612, Sept. 12, 1980]

§ 864.7280 Factor V Leiden DNA mutation detection systems.

(a) *Identification.* Factor V Leiden deoxyribonucleic acid (DNA) mutation detection systems are devices that consist of different reagents and instruments which include polymerase chain reaction (PCR) primers, hybridization matrices, thermal cyclers, imagers, and software packages. The detection of the Factor V Leiden mutation aids in the diagnosis of patients with suspected thrombophilia.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance entitled ''Class II Special Controls Guidance Document: Factor V Leiden DNA Mutation Detection Systems.'' (See § 864.1(d) for the availability of this guidance document.)

[69 FR 12273, Mar. 16, 2004]

§ 864.7290 Factor deficiency test.

(a) *Identification.* A factor deficiency test is a device used to diagnose specific coagulation defects, to monitor certain types of therapy, to detect coagulation inhibitors, and to detect a carrier state (a person carrying both a recessive gene for a coagulation factor deficiency such as hemophilia and the corresponding normal gene).

(b) *Classification.* Class II (performance standards).

[45 FR 60613, Sept. 12, 1980]

§ 864.7300 Fibrin monomer paracoagulation test.

(a) *Identification.* A fibrin monomer paracoagulation test is a device used to detect fibrin monomer in the diagnosis of disseminated intravascular coagulation (nonlocalized clotting within a blood vessel) or in the differential diagnosis between disseminated intravascular coagulation and primary fibrinolysis (dissolution of the fibrin in a blood clot).

(b) *Classification.* Class II. The special control for this device is FDA's ''In Vitro Diagnostic Fibrin Monomer Paracoagulation Test.''

[45 FR 60614, Sept. 12, 1980, as amended at 52 FR 17733, May 11, 1987; 65 FR 17144, Mar. 31, 2000]

§ 864.7320 Fibrinogen/fibrin degradation products assay.

(a) *Identification.* A fibrinogen/fibrin degradation products assay is a device used to detect and measure fibrinogen degradation products and fibrin degradation products (protein fragments produced by the enzymatic action of plasmin on fibrinogen and fibrin) as an aid in detecting the presence and degree of intravascular coagulation and fibrinolysis (the dissolution of the fibrin in a blood clot) and in monitoring therapy for disseminated intravascular coagulation (nonlocalized clotting in the blood vessels).